

PATENT
USSN 09/721,506
002616US; 018-210c

REMARKS

This paper is responsive to the Office Action dated January 11, 2006, which has been made final.

Claims 75-78, 80, 83-86, 88, 91-94, 96, and 101-104 were previously pending. Upon entry of this amendment, claims 83-86, 88, 91-96, 101, and 103-104 are newly cancelled, being replaced by new claims 105-108, which fall within the group under examination. Accordingly, claims 75-78, 80, 102, and 105-108 are pending, with claim 80 being withdrawn from examination.

Further consideration and allowance of the application is respectfully requested.

Interview Summary

The undersigned is grateful to Examiner Sisson for a cordial and constructive interview regarding this application conducted at the Patent Office on May 16, 2006.

It was agreed that the wording of the claims amended here reflected the Written Description Guidelines, as reciting a degree of identity with the prototype sequence, *and* a function (telomerase catalytic activity, or the ability to elicit an immune response to hTRT). Thus, they meet the written description requirements of 35 USC § 112 ¶ 1. The degree of identity recited in claims 75, 102, and 108 is determined in relation to *the full length of SEQ. ID NO:2*, which meets the clarity requirements of § 112 ¶ 2. It was also agreed that the format of claim 107 is proper, since SEQ. ID NO:13 is a subsequence of SEQ. ID NO:2.

It was agreed that the proposed changes would be presented by applicants in this second 37 CFR § 1.116 Amendment. Applicants' representative undertook to address the double patenting rejections under separate cover.

Rejection under 35 USC § 112 ¶ 1

The claims under examination stand rejected as failing to comply with the written description requirement of § 112 ¶ 1.

For reasons stated previously, it is applicants' position that the claims as previously presented met all the requirements of 35 USC § 112 ¶ 1. Nevertheless, to focus coverage on embodiments of the invention of current commercial interest, the claims are herein amended to cover sequences that are at least about *95% identical over the full length of SEQ. ID NO:2*, and equivalents of such variants for which coverage is allowed in accordance with the relevant case law. The amendments are made

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without prejudice. Applicants reserve the right to reintroduce claims to other embodiments of the invention in this or any related application at a later time.

Claims 75-78 and 102 further require that the claimed fragments have *telomerase catalytic activity when complexed with a telomerase RNA*, as can be determined *inter alia* by the telomerase enzyme activity assays detailed in the specification. Thus, these claims recite a degree of identity with the prototype sequence, *and* a function, and therefore comply with the Written Description Guidelines.

Withdrawal of the § 112 ¶ 1 rejection of these claims is respectfully requested.

Claims 105-108 replace the cancelled claims. They have been modified somewhat from the claims presented previously, but meet the requirements for patentability by the same reasoning.

These claims again recite both structure and function, in accordance with the Written Description Requirements. The function recited here is an alternative to the function recited in claim 75: namely, the property of being able to elicit *an immune response against hTERT* (upon administration to a suitable host). The use of SEQ. ID NO:2 to elicit an antibody response is described in the specification, for example, in U.S. Patent 6,166,178 (of which this application is a continuation) in cols. 71-75 and col. 89. The skilled reader will appreciate that polypeptides of 100 amino acids or more in length typically have a number of different Class I and Class II epitopes, and will be able to elicit a specific immune response in a suitable host according to standard methodology.

Claim 106 refers to a particular subfragment of the full-length hTERT protein designated SEQ. ID NO:13. This application is a continuation-in-part of U.S. Patent 6,261,836, and incorporates it by reference. The '836 patent lists the same hTERT fragment as SEQ. ID NO:67. The '836 patent specifically refers to the use of this fragment to generate an immune response at col. 8, lines 30-36.

Claim 107 refers to the rest of SEQ. ID NO:2 not contained in SEQ. ID NO:13. This is in accordance with MPEP § 2173.05(i), which states: "If alternative elements are *positively* recited in the specification, then they may be explicitly *excluded* in the claims: See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 194 (CCPA 1977) ('[the] specification, having described the whole, necessarily described the part remaining.')."

Accordingly, claims 105-108 also meet the patentability requirements of 35 USC § 112 ¶ 1.

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Double patenting

Certain claims stand provisionally rejected for double patenting in view of what is claimed in U.S. Patent 6,337,200, USSN 09/438,486 (now U.S. Patent 6,927,285) and USSN 10/054,295 (now U.S. Patent 6,921,664). Certain claims stand provisionally rejected for double patenting in view of what is claimed in USSN 09/721,477, USSN 10/044,692, and USSN 10/877,124.

Applicants have responded to this rejection previously. As promised during the interview, applicants will address this matter further under separate cover.

Request for Rejoinder:

Claim 80 is a method claim that depends from and incorporate the limitations of product claim 75. Applicants hereby request that this claim be rejoined into the application, upon determination that the product claim is patentable, in accordance with MPEP § 821.04.

Request for Interview

In the event that the Examiner determines that there are other matters to be addressed, the undersigned hereby requests an interview by telephone.

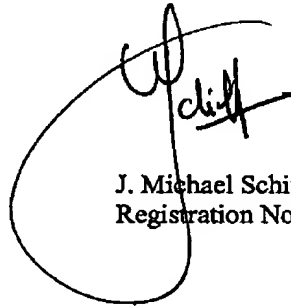
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Fees Due

No fee is believed payable with respect to the entry and consideration of this Amendment.

Nevertheless, in the event that the Patent Office determines that an extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Michael Schiff", is written over a large, loopy circular mark.

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May 24, 2006